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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

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01/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,651	Applicant(s) KINDERMANN ET AL.	
	Examiner /Mark L. Berch/	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/31/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

11472845 514/313 wrong; these are ISOquinolines. 546/13 – cant find Boron R10a can be morph and ex249 has it (also clm32) & azepansulfonyl – ex239. SO need search and Xref & Xref on corres intermediates. Clms 19-21 withdrawn but =ed; make official rejoinder on record, use form pgh. Index of clms has 29 = but its canceled. PTO37 has claims 8,9but its 7,8.. Class 564 appears with no subclass. Need A61P for =ed method clms. C07F217/16 doesn't exist. Need C07D for isoquin + ring not fused - clm 32

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2(part), 3-5, 8-28(part), 29-30, 31(part) drawn to R1-R2= purine.

Group II, claim(s) 1-2(part), 6, 8-28(part), 31(part) drawn to R1-R2= triazolopyrimidine.

Group III, claim(s) 1-2(part), 7, 8-28(part), 31(part) drawn to R1-R2= aminopyrimidine

Group IV, claim(s) 1-2(part), 8-28(part), 31(part) drawn to R1-R2= others.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each R1-R2 groups represents a separate core and provides a distinct special technical feature. Group IV would includes numerous groups such as indole, pyridine, triazine, quinazoline, pteridine, quinoline, tetrazine, benzimidazoles, triazole, etc. During a telephone conversation with Mike Davis on 11/20/2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5, 8-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or

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more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

In this case, reason (a) clearly applies. The classification is as follows:

Group I: 544/265, 269, 270, 271, 272, 276

Group II: 544/254

Group III: 544/319

Group IV: 544, 546, 548 and others, various subclasses.

Applicant is advised that the reply to this requirement to be complete must include

- (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

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and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 1-2, 8-28, and 31 are rejected as being drawn to an improper Markush Group. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction. This does not constitute an art recognized genus. Because of the marked structural differences at a part of the molecule essential for utility, the claims are deemed to lack unity of invention (see *In re Harnish*, 206 USPQ 300). The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter will overcome the rejection. This can be done by setting R1 as purine.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 15, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by 20040115130.

This reference basically discloses applicants' invention for the circumstance where the nucleobase is guanine, X is O and R3 is phenylene; see paragraph 18-21, and examples in Figure 1(E)

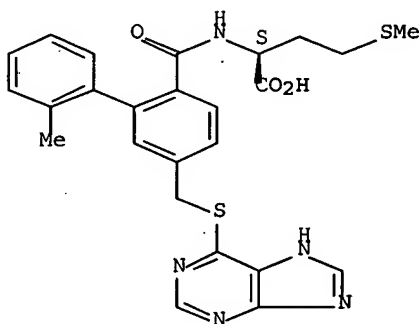
The Keppler publication is not applied as it is not prior art; The claims are supported by the priority document.

Claims 1-4, 15, 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker.

Note the Table 1 compounds 3-18, corresponding to X=S, R3 as phenylene, and the labels as the amide or urea and also as the terminal group, the halogen (e.g. compound 3), or the sulfonyl halide (compound 4). Alternatively, the amide or urea will qualify as the linker, thereby anticipating claim 15.

Claims 1-4, 15, 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gabriel.

The reference discloses benzoyl substituted methionine compounds. On page 377, see the substituent in example 747. That works out to the following compound:



This gives a linker with the amide, and the carboxy and the methylthio as labels, and the amide will qualify as label as well.

Claims 1-5, 26-27, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaidyanathan.

See compounds [^{18}F]6 in scheme 1, and compounds 6-13 on page 872. These are guanines based on $\text{X}=\text{O}$ (hence anticipating claim 5), with the substituent at the far right being the label.

Claims 1-5, 26-27, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5691307.

See Formula I, where X would be the label, or linker plus label, and Formula 3 and 4, where X4 is the label (note that X1 can be H). Note the halobenzyl species in Table 2, the formylbenzyl of example 12, and the hydroxybenzyl of example 11.

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Claims 1-4, 15, 24-28, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Damoiseaux.

See type 2, represented by compound 8. These are guanine based oligonucleotide with X=O (hence anticipating claim 5), with the biotin substituent at the right end being the label. In addition, the amide linkages in 2 would also qualify as a second label. The intermediate of formula 4 also meets the claim language. (A cleaner copy of this reference is made of record)

Claims 1-5, 26-27, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibson.

See compound 19, with R3 as alkenyl and the phenyl ring as the label, 28 with R3 as cycloalkenyl, and the terminal isopropenyl groups as the label, 33-35 with R3 as phenyl and the amino, chloro or methoxy groups as label.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over 20040115130.

The reference is discussed above. The polyethylene glycol chain of these claims is taught in paragraph 0026, and hence would be obvious.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are 1-5, 8-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. R3 is defined as having an "unsaturated alkyl or cycloalkyl ... group with the double bond ..." An alkyl group cannot have a double bond, nor can a cycloalkyl. Suggested is alkenyl or cycloalkenyl.
2. The term "label" in claim 1 is vague. Pretty much any group which is capable of reacting with anything at all can be a label. As a practical matter, a label can be pretty much anything except H, which is not normally called a label. There is no way of knowing what, if anything is required by such a term. How could one show that something is not in fact an label? There are UV labels, a fluorescent labels, phosphorescent labels and other types of chemiluminescent labels. There are spin labels or other paramagnetic labels, along with ferromagnetic, and diamagnetic labels. There are enzymatic labels (such as glyucose oxidases), antigens, antibodies, and haptens as labels. There are light scattering labels (e.g. quantum dot or nanoparticle) and calorimetric labels . There are

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an array of chemically reactive labels such as sulfhydryl-reactive labels and amine-reactive labels. There are photolabile labels, photoreactive labels. What is a label really depends on what the detection system is. Almost anything can be a label unless it is chemically and radioactively and wave-energy inert.

3. The definition of label in claim 2 is also unclear. Note that L is a moiety, yet most of the choices are molecules, e.g. "a molecule which is one part....". The term "a library...." Makes so sense, since a library is a collection, not a moiety or even a molecule. The term "a molecule that is suspected to interact with other biomolecules" is unclear because it is not clear what a "biomolecule" is, and because "interact" is an extremely broad term, as it would cover even hydrogen-bonding and other weak van der Waals interactions. Another term has "desirable" --- but desirable by what standard? Nearly all the terms are unclear.
4. The term "linker" is indefinite. It states where something is, but not what it is. It is not even clear whether the term does or does not cover a valence bond itself.
5. R3 is a divalent group, and must be defined as such, e.g. "phenylene" in claim 2.
6. Also in this regard, the term "1-alkenyl" doesn't make sense, since one does not know which direction the numbering system goes.
7. R3 is required by claim 1 to have a double bond, but claim 2 lists the alkynyl group, which has a triple bond. Did applicants intend triple bond as an alternative in claim 1? Likewise claim 14 and 29.
8. R4 choice b) has an inconsistency. It has "and the adjacent carbon atoms are substituted by oxo" giving an amide. Because of the plural, one actually gets C(O)-NH-C(O), which is an imide.

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9. The same issue arises in c), so that one gets C(O)-O-C(O), which is an anhydride, not an ester.
10. The claim 17 term "dendritic structures" is indefinite. There is no clear guideline as to what degree of branching is needed to qualify as a dendrite.
11. Claim 26 does not define an actual process; no steps are given.
12. The term "orthogonally" in claim 28 is of unknown meaning.
13. In claim 28, Deprotection of what?
14. The phrase following "so that...." in claim 28 is unclear. Is there an actual step here? In principle, any "functionality" can be chemically manipulated. The very nature of a functionality is that it can react, i.e. be manipulated to attach something.
15. Claim 31 is very unclear. It is unknown what "manipulating" is supposed to cover. How can a protein be "incorporated" into another fusion protein?

Specification

The abstract is objected to as failing to set forth what the invented compounds actually look like. The term "O-alkyl guanines" is too vague. Suggested is the claim 1 text, optionally replacing the R1-R2 text with "guanine".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/
Primary Examiner
Art Unit 1624

6/20/2008